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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Minneapolis District Office
Central Region
212 Third Avenue South
Minneapolis, MN 55401
Telephone: (612) 334-4100
FAX: (612) 334-4134

March 10, 2004

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 04 - 17

Lyle Holschbach, DVM
Paul R. Calonder, DVM
Keith C. Tuttle, DVM
Terry M. Hruby, DVM
John E. Degner, DVM
Ted A. Greif, DVM
Partners
Veterinary Associates, LLC
19922 U.S. Highway 10
Reedsville, Wisconsin 54230

Dear Drs. Holschbach, Calonder, Tuttle, Hruby, Degner and Greif:

On October 3, 8, 17 and 21, investigators from the Food and Drug Administration (FDA) conducted an investigation involving the use of drugs in your veterinary practice. That investigation revealed that you caused animal drugs to be unsafe under Section 512(a) of the Federal Food, Drug and Cosmetic Act (the Act) and adulterated within the meaning of Section 501(a)(5) of the Act because the drugs were used in a manner that did not conform with their approved uses or the regulations for Extralabel Drug Use in Animals, Title 21, Code of Federal Regulations (21 C.F.R.), Part 530. The investigation also revealed that you caused animal drugs to be misbranded within the meaning of Section 502(f)(1) of the Act.

The extralabel use of approved veterinary or human drugs in animals is permitted only if it complies with Sections 512(a)(4) and 512(a)(5) of the Act and 21 C.F.R. Part 530. Our investigation found that Veterinary Associates failed to comply with 21 C.F.R. Part 530 in that:

1. You prescribed gentamicin sulfate products, including compounded products containing gentamicin sulfate, for extralabel use in dairy cows without establishing a substantially extended withdrawal period, supported by appropriate scientific information as required by 21 C.F.R.

§ 530.20(a)(2)(ii). Veterinary Associates was not able to support the labeled withdrawal times (180 days for meat for one gentamicin sulfate product and 90 days for meat for another) with scientific information.

2. You prescribed sulfadimethoxine 12.5% oral solution for intravenous use in lactating dairy cattle, which is an extralabel use. The extralabel use of sulfonamide drugs in lactating dairy cattle is prohibited by 21 C.F.R. § 530.41(a)(9). While approved uses of sulfadimethoxine drugs, listed in 21 C.F.R. § 520.2220a, are not prohibited by this regulation, your use was not an approved use. We are enclosing a copy of 21 C.F.R. § 520.2220a for your reference.

3. A product ("Orange Juice") containing sulfamethoxazole and trimethoprim was compounded and prescribed for extralabel use in lactating dairy cattle. Sulfamethoxazole is prohibited for extralabel use in lactating dairy cattle per 21 C.F.R. § 530.41(a)(9).

4. The labeling for compounded products did not contain the established name of each active ingredient as required by 21 C.F.R. § 530.12(b). Compounded products containing gentamicin listed the active ingredient as "aminoglycoside." Also, a compounded product ("Orange Juice") containing dexamethasone did not list dexamethasone as an ingredient.

Because you failed to comply with the requirements of 21 C.F.R. Part 530 in compounding, prescribing, and dispensing animal drugs, your clients used new animal drugs in an unapproved manner without meeting the requirements for extralabel use set forth in Section 512(a)(4)(A) and 21 C.F.R. Part 530, thereby rendering the drugs unsafe under Section 512 of the Act and adulterated under Section 501(a)(5) of the Act. In addition, you caused new animal drugs to be misbranded within the meaning of Section 502(f)(1) of the Act in that they were dispensed for extralabel use, within the meaning of 21 C.F.R. § 530.3(a), and without the labeling required by 21 C.F.R. § 530.12.

It is not necessary for you to personally ship an adulterated drug in interstate commerce to be responsible for a violation of the Act. The fact that you caused the adulteration of drugs that were sold in interstate commerce is sufficient to hold you responsible for a violation of the Act.

The above is not intended to be an all-inclusive list of violations. As licensed veterinarians, you are responsible for complying with the requirements of the Act, including the extralabel use regulations promulgated under the Act. You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction.

We have enclosed a copy of 21 C.F.R. Part 530 for your reference. We strongly suggest that you review 21 C.F.R. Part 530 and become familiar with all of its requirements so that you can prevent future violations of the Act.

We have received Dr. John Degner's letter dated October 29, 2003, which replied to the form FDA-483 issued on October 21, 2003. A copy of that letter is attached. The corrective actions that were reported, if fully implemented in a timely manner, appear to be adequate to address the concerns cited on the form FDA-483. In your response to this Warning Letter, please provide an update on the status of the corrective actions described in Dr. Degner's letter, and state your plans for correcting the violations noted above under numbers 3 and 4.

You should notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Also include copies of any available documentation demonstrating that your corrections have been made.

Your reply should be directed to Compliance Officer Timothy G. Philips at the address indicated on the letterhead.

Sincerely,

W. Charles Becoat
Director
Minneapolis District

TGP/ccl

Enclosures: 21 C.F.R. § 520.2220a
21 C.F.R. Part 530
Degner to Philips, 10/29/03

xc: Robert Ehlenfeldt, DVM
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